

## **Remarks**

This Amendment is submitted with a Request for Continued Examination. The amendments above and the remarks below are in response to the final Office Action mailed December 14, 2007. Applicant has withdrawn the application from appeal in order to correct errors noted concerning the use of “distal” rather than “proximal” in claims 5 and 12, to address other matters in the claims, and to address the Examiner’s position, particularly with regard to the interpretation of a head having a “triangular configuration.” No new matter has been added by the amendments. In light of the amendments and subsequent remarks, applicant respectfully requests reconsideration and allowance of the pending claims.

## **Claim Rejections - 35 USC § 102**

Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kapandji (FR 2 660 856 A1). The Examiner takes the position that Kapandji discloses an implant 1 comprising a stem 20 and a head 4 (see Fig. 2), the implant having holes 26 passing through positions near both ends of the stem 20 and being capable of accepting a suture, and the head 4 including a 200 degree arc. The Examiner considers component 30 to be a portion of the platform or an extension, and further takes the position that component 30 includes holes 27 through which a suture could be passed.

In the Final Office Action, the Examiner took the position that while the inner portion of the head of Kapandji has a cavity, this does not change the fact that the outer surface or extent thereof defines a head. The Examiner further explained that the vertex and adjacent surfaces where the convex portion meets the planar face surrounding the cavity define what can be seen as a “triangulated configuration,” citing Kapandji Fig. 2.

With regard to the Examiner's interpretation of Kapandji in the final office action, applicant does not agree that Kapandji teaches a head within the meaning of applicant's specification (for the reasons discussed below and in applicant's previous response), much less a head having "triangulated configuration." Nonetheless, applicant has amended the claims to provide that applicant's head 14 has a triangulated portion when viewed from a distal end. Support for this amendment is found in Figure 1, which indicates that if the head 14 were viewed from the distal end, the head 14 would have a triangulated portion. Additionally, the term "triangulated portion" has been substituted for "triangulate configuration." Throughout the specification, the head 14 is described as having a "triangulated portion" rather than a "triangulated configuration." The preferred embodiment shown in the drawings has both a "triangulate portion" and an arc portion, and the use of "triangulated portion" therefore is believed to more particularly distinguish over the prior art.

As previously submitted, it is respectfully suggested that Kapandji is being misinterpreted, and that Kapandji does not teach all of the limitations of the claimed invention. As can be seen in Figures 2, 3 and 4 of Kapandji, the cited reference teaches an implant that differs markedly in structure and function from that of the claimed invention. The Kapandji implant consists generally of a female part 2, a fixation means 30 for the female part 2, a male part 3, and a fixation mean 7 for the male part. The female part 2 is implanted in a diaphyseal region of the ulna and is configured to articulate with the male part 3, which is implanted in a distal portion of the ulna. As shown in Kapandji Figures 3 and 4, the separate fixation means 7, 30 are configured to receive fixation screws 25, 44 in alignment with through bores in the stems 20, 40 of the respective female and male parts 2, 3. The Examiner interprets Kapandji component 4 as being a "head," but this component of Kapandji is in fact an open cavity 4 ("cavité ouverte

4”) that is formed in a well 10 (“un puits 10”). In the final office action, the Examiner took the position that although this component of Kapandji has a cavity, this does not change the fact that the outer surface or extent thereof defines a head. However, as applicant previously noted, the Kapandji well 10 and its open cavity 4 are integrally formed with the stem 20 of the female part 2, and are configured to articulate with the head 5 of the male part 3, as clearly shown in Figures 3 and 4, not with a sigmoid notch of the distal radius. In claim 1, applicant’s head is further “configured for attachment to the second end of the stem,” which means, when interpreted according to applicant’s specification, that the head is a *separate* component that is configured for attachment to the second end of applicant’s stem. Nor does Kapandji teach “a head having a triangulated portion when viewed from a distal end.” As discussed above, applicant has attempted to address the “triangulated portion” through claim amendments. Thus, applicant respectfully suggests that Kapandji’s open cavity 4 cannot be interpreted as disclosing or functioning as a separate head having a triangulated portion within the meaning of applicant’s claimed invention.

As previously noted, applicant is of the view that Kapandji does not teach various other elements of at least claim 1. Applicant agrees with the Examiner’s observation that Kapandji’s stem component 20 has through holes through which sutures are capable of being passed, but does not agree that Kapandji’s screw holes are positioned in the manner claimed in claim 1. As can be seen clearly in Kapandji Figures 3-4, the Kapandji holes are lodged in the intramedullary canal of the bone, where they are not positioned at a second end for receiving sutures attaching the implant to soft tissue.

Anticipation under 35 USC 102(b) requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.

*Lindermann Maschinenfabrick GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984); MPEP § 2131. The prior art reference must be such that a person of ordinary skill in the field of the invention would consider there to be no difference between the claimed invention and the reference disclosure. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the prior art reference under 35 USC 102(b) must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ.2d 1241, 1245 (Fed. Cir. 1986). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 48 USPQ.2d 1321, 1328 (Fed. Cir. 1998).

It is respectfully suggested that Kapandji does not teach each and every element of the claimed invention, and that Kapandji does not enable the claimed invention. Accordingly, a prima facie showing of anticipation has not been made.

### **Claim Rejections - 35 USC § 103**

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooney, III et al. (6,302,915 B1) in view of Stubstad (3,745,590). The Examiner takes the position that Cooney discloses the claimed invention except for the use of suture holes in portions of the device other than the head and except for the head having a through-bore. The Examiner takes the position that Stubstad discloses a similar device 10 and teaches attaching a ligature or suture 22 through both the head 11 and the stem 16 platform 19 structure in order to provide a continuity of strength through the prosthesis and resist dislocation of the joint to be corrected

while still providing unrestricted natural motion, citing Fig. 2; col. 1, lines 5-11; and col. 2, lines 44-47.

Applicant traverses on grounds that elements and arrangements of the claimed invention are not taught by the cited references, and that these elements and arrangements can be supplied only by relying on the teachings of applicant's disclosure to arrive at the claimed invention.

As previously noted, applicant does not agree with the Examiner's interpretation of Cooney and Stubstad. As far as applicant can determine, neither Cooney nor Stubstad teach "a head having a triangulated portion when viewed from a distal end." As previously noted, Cooney specifically teaches a spherical structure for Cooney's head 12, as follows: "By cross-referencing FIGS. 1, 2 and 3A it can be seen that the head 12 is generally crown shaped and formed with a curved surface 18 for articulation with the sigmoid notch 20 of the distal radius 22." (Cooney, Col. 5, lines 4-8). As far as applicant can determine, Cooney provides no suggestion for providing any configuration for the head 12 other than spherical. In the final Office Action, the Examiner noted that "In addition, in the same way that the Kapandji reference can be seen as showing a 'triangulated configuration,' so too can the Cooney reference, also at the vertex of the planar portion and the convex portion (as exemplified above in the diagram; cf. Cooney Fig. 3A)." Applicant does not understand this observation, and requests clarification or reconsideration in view of applicant's claim amendments. Because the cited references fail to teach a head as claimed, it is respectfully submitted that the proposed combination of Cooney in view of Stubstad fails to establish a prima facie case of obviousness.

As previously noted, applicant is further of the view that other claim elements are simply not found in the Cooney and Stubstad references, including for example "suture holes [26, 24] being provided at the proximal and distal ends of the extension [34]" and "the head includ[ing] a

bore extending completely therethrough.” The Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant of Cooney with holes in portions other than the head, such as the stem and platform, in view of Stubstad, in order to provide a continuity of strength through the prosthesis and resist dislocation of the joint to be corrected while still providing unrestricted natural motion. Although the Examiner takes the position that Stubstad teaches attaching a ligature or suture 22 through both the Stubstad head 11 and stem 16 platform structure 19, applicant can locate no such teaching, including in the portions of Stubstad that are cited by the Examiner (Fig. 2; col. 1, lines 5-11; and col. 2, lines 44-47). Stubstad discloses a unibody implant that clearly lacks many of the claimed features, such as an extension 34 and a head 14 configured for attachment to the extension 34. The Stubstad implant is for use in joints that require an unrestricted orbiting motion, such as the trapezium and lunate bones of the wrist. Stubstad makes no mention of the ulna or radius. Stubstad describes a unibody implant in which an affixed “ligamentous element” protrudes substantially along an edge of the articulating surface of the implant. Stubstad does not discuss providing holes in the implant, but instead consistently describes the ligamentous element as being integral with or affixed to the implant. By disclosing an affixed ligamentous element, Stubstad appears to teach away from providing a through bore for receiving a suture. Applicant fails to appreciate how Stubstad’s teaching of an implant having an integrally attached ligamentous structure somehow adds to the teaching of Cooney.

In the final Office Action, the Examiner clarifies that Cooney teaches holes as an attachment means, while Stubstad is cited as teaching the attachment of the suture at both the head and the stem/platform structure. The Examiner takes the position that the way that Stubstad attaches the suture 22 to the device is not material, because Stubstad is not being cited for that

proposition, but rather for the concept of attaching the suture 22 at the noted locations. Applicant does not follow this reasoning, and requests further clarification. It does not appear to applicant that Stubstad teaches attaching sutures at both the head and stem structure. It remains unclear to applicant how Stubstad can be interpreted as teaching or suggesting putting suture holes in both a head and stem, much less in the arrangement of the claimed invention.

With regard to the particular locations of the various holes, the Examiner maintains the position that it also would have been obvious to have positioned these at any of various locations on the device, since it has been held that mere relocation of parts of an invention involves only routine skill in the art, citing *In re Japikse*, 86 USPQ 70. Applicant is not merely relocating suture holes, but is claiming placement of the suture holes in the context of an implant that has a different structure and function from that of the cited references. Applicant remains of the view that applicant's specification, rather than the cited references, is being used to provide a reason for modifying the cited references to provide holes in the claimed locations. In *KSR*, the Supreme Court cautioned that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *Id.*, 127 S.Ct. at 1742, citing *Graham*, 383 U.S. at 36.

The Examiner further maintains the position that it would have been obvious to have selected a bore depth in the head within a range resulting in a through bore, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, citing *In re Aller*, 105 USPQ 233. In the final Office Action, the Examiner concludes that providing a through bore is an obvious modification and that doing so would hardly require a person of ordinary skill in the art to have to consult the applicant's disclosure to understand how or why to change the dimensions.

As previously noted, applicant fails to appreciate how a through bore can be considered to be an optimum or workable range, when in fact a through bore is a different structure that enables different functions, such as securing a separate head 14 via a suture passed through a through hole 24 in the distal end 30 of the extension 28. Applicant again remains of the view that applicant's specification, rather than the cited references, is in fact being consulted in order to modify the cited references to provide a through bore.

Applicant also notes dependent claims 10 and 14, which have been amended to further distinguish over the prior art by providing "at least a portion of the head is covered with an ingrowth coating at least near the triangulated portion to promote ingrowth with the soft tissues."

Thus, applicant respectfully submits that at least one limitation of the claimed subject matter of Claims 1-20 is neither taught nor suggested in the cited art. To establish *prima facie* obviousness of a claimed invention, all the claimed limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). It has been noted repeatedly by the courts that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 165 USPQ 494,496 (CCPA 1970). In *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 167 L.Ed.2d 705, 82 USPQ.2d 1385 (2007), the Supreme Court recently held that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.*, 127 S.Ct. at 1741. Accordingly, in the absence of a demonstration of elements being known in the prior art, *prima facie* obviousness is not established.

In *KSR*, the Supreme Court further recognized that there is no inconsistency between the idea underlying the longstanding teaching-suggestion-motivation test and the *Graham v. John Deere* analysis, provided that the teaching-suggestion-motivation test is not rigidly applied. *Id.*,



127 S.Ct. at 1741. *KSR* held that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *Id.*, 127 S.Ct. at 1741. In the present case, where elements and arrangements of the claimed invention are not found in the references, applicant respectfully suggests that the teaching-suggestion-motivation test should be applied. While the Examiner has attempted to provide reasons for the proposed combinations of the cited references, it is respectfully suggested that these reasons are based on applicant’s teachings, not motivations, suggestions or teachings found in the cited art. In the absence of a reason in the cited references that would have prompted a person of ordinary skill in the field to combine the elements in the manner of the claimed invention, much less to supply the missing elements, it is respectfully suggested that a *prima facie* showing of obviousness has not been established.

## Conclusion

In view of the amendments and remarks presented above, it is respectfully submitted that all of the present claims of the present application are in condition for immediate allowance. It is therefore respectfully requested that a Notice of Allowance be issued. The Examiner is encouraged to contact applicant's undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

This response has been filed with a petition for a one month extension of time. It is believed that no further extension is required, but if an extension is required, applicant hereby requests an appropriate extension of time. If any fees or credits are due, the Commissioner is authorized to charge or deposit them to Deposit Account No. 502795.

Respectfully submitted,

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